UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

CHARLES M. SARAFIN, Individually And On Behalf Of All Others Similarly Situated,	)	
Plaintiffs,	)	
	)	**No. 3:11-0653**
v.	)	**Judge Sharp**
BIOMIMETIC THERAPEUTICS, INC., SAMUEL E. LYNCH, and LAWRENCE E. BULLOCK,	)	
Defendants.	)	

MEMORANDUM

Plaintiff Charles M. Sarafin brings this action under the Securities and Exchange Act of 1934 on behalf of himself and others who purchased or acquired the common stock of Defendant BioMimetic Therapeutics, Inc. ("BMTI" or the "Company") between October 14, 2009 and May 15, 2011 (the "class period"). The crux of the 183 paragraph, 70 page Amended Complaint is that Defendants[1] knowingly and/or recklessly made material misrepresentations to investors about the clinical trials for its flagship product Augment™ Bone Grafting ("Augment"), as well as the prospects for approval of Augment by the Food and Drug Administration ("FDA").

Defendants have filed a Motion to Dismiss (Docket No. 39), to which Plaintiff has responded in opposition (Docket No. 44), and Defendants have replied (Docket No. 50). On September 21, 2012, the Court heard oral argument and, for the following reasons, will grant Defendants' Motion to Dismiss.

[1] Defendants include, not only BMTI, but also its founder, President and Chief Executive Officer Samuel E. Lynch, and Lawrence E. Bullock, its Chief Financial Officer.

I. FACTUAL BACKGROUND

The factual allegations in the Amended Complaint are as follows:

Bone grafting is a $2.5 billion market in the United States, with one million bone graftings performed annually in North America. Of those, an estimated 250,000 foot and ankle surgeries requiring bone grafting are performed, with that market alone being valued at $500 million. BMTI desires to enter the United States market through its core product Augment.

Augment is a fully synthetic, off-the-shelf bone growth factor product for the surgical treatment of foot and ankle bone defects. More specifically, Augment is a combination product (device and biologic drug) consisting of recombinant human platelet-derived growth factor-BB ("rhPDGF"), packaged together with a β-tricalcium phosphate matrix ("B-TCP"). B-TCP provides a scaffold on which new bone may grow, while rhPDGF stimulates the growth of osteoblasts which are the cells responsible for bone formation.

Presently, the standard of care for foot and ankle fusion surgeries requiring supplemental graft material is the autologous bone graft, or autograft. In an autograft, surgeons harvest bone or tissue, generally from another part of the body, and this often requires a second surgical procedure. Augment, if proved to be safe and effective, would likely be a preferable procedure because it does not require the patient to be subjected to the additional invasive procedure that is needed to harvest the graft material.

Augment is a key to BMTI's success as a company.[2] For Augment to become a successful device used in bone grafting operations in the United States, however, it needs FDA approval.

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[2] In 2010, BMTI generated only $1.5 million in total revenues, most of which was derived from royalty and licensing fees related to a product it had sold in 2008. That same year, it incurred a $33.9 million loss.

A. General FDA Approval Process

The FDA, through the Premarket Approval ("PMA") process, looks at manufacturing information, data from preclinical studies (*i.e.*, animal and laboratory studies), and clinical trials to determine whether the sponsored device is safe and effective for its intended use. To conduct clinical trials, a sponsor must receive an investigational device exemption ("IDE") from the FDA. This requires the sponsor to provide the FDA with a study plan or protocol that governs how clinical studies are to be performed and analyzed.

After a PMA is submitted, the FDA begins its substantive review of the application. During the review process, the agency will notify the sponsor via "deficiency letters" of its concerns, and whether more information is required to complete the review. The sponsor may request to meet with the FDA within 100 days of the filing of the PMA to discuss the status of the application.

During the review process, the FDA may refer the application to an outside panel of experts, and provide the panel with a data package on the product. At a public meeting, both the FDA and the sponsor present their interpretation of the data that has been compiled. The panel then votes on whether the product should be approved for use, taking into consideration the product's safety and effectiveness, and whether its benefits outweigh the potential risk.

In making its determination of whether the device can be used on patients, the FDA considers, but is not bound by, the panel's recommendation. The FDA may approve the device, find it "approvable" upon the submission of specific aditional data, or "not approvable" because of major problems.

B. Alleged Deficiencies In Augment Protocol

BMTI submitted a modular PMA to the FDA, by which different sections of the application

were presented separately to the FDA. On June 28, 2009, it submitted two modules, containing preclinical and manufacturing data, and submitted the third and final module containing clinical data on February 17, 2010.

BMTI conducted a clinical trial of Augment that began on April 9, 2007 and ended on January 18, 2010. That trial was designed to evaluate Augment's effectiveness and safety in foot and ankle fusion surgeries, and the device was considered effective if, 24 weeks after surgery, the rate of adequately healed patients was no worse than or equal to the rate of adequately healed patients who received an autograft. A fusion was considered to be effective if there was at least 50% bone bridging across the joint space, based on computed tomography ("CT") scans.

Under the binding protocol presented to the FDA, the "primary effectiveness analysis" was to be performed using as specified Intent-to-Treat" ("ITT") population, based upon the initial treatment assignment (*i.e.*, Augment or autograft), and not on the treatment or non-treatment actually received. However, and unbeknownst to the FDA, BMTI based its analysis upon a "modified Intent to Treat" ("mITT") population that was a subset of the ITT population from which certain patients were excluded. The ITT population, instead of being the primary basis for effectiveness as required by the submitted protocol, was used as supportive evidence.

The switch in the population database skewed the results, making them more favorable than they would have been under the originally proposed protocol. While Augment was considered effective in the mITT population, it did not achieve statistical significance for effectiveness in the ITT population.

The undisclosed switch in the protocol population was not the only problem with Augment's PMA process. Other problems and shortcomings included:

→The pool of participants in the clinical trial was "underpowered" or too small to yield adequate effectiveness data. Based on an earlier pilot study, BMTI knew that the pool needed to properly determine the difference in the rates of successful fusion between Augument and autograft patients had to be in excess of 700 participants, instead of the "400 or so people tested in the study." Even though BMTI could have remedied this problem by increasing the study size, it chose not to do so, and, in fact, took away the independent data monitoring committee's power to increase the study size because "the company was concerned that any interim look at the data may have led to FDA questioning the validity of the blind, or imposing statistical penalties on the trial."

→ The clinical trial's effectiveness data were undermined by the lack of baseline imaging against which to compare post-surgical results because, without baseline CT scans, there was no way to accurately determine whether treatment was a success (i.e. 50% osseous bridging).

→ BMTI violated both the protocol and federal regulations, and did not heed "good clinical practices" when enrolling certain patients in the pivotal clinical study. There were some 1,457 protocol deviations for the 456 study subjects. Regulatory and standard operating procedure violations in Augment clinical trial included (1) inadequate training of investigators; (2) improper documentation of patient enrollment; and (3) missing or lost documentation.

→ The FDA conveyed serious concerns about the potential risk of cancer developing in Augment patients due to the fact that Regranex, a product similar to Augment that also contained rhPDGF, was associated with increased deaths from pre-existing cancer. In 2008, the FDA issued a public warning about its ongoing safety review of Regranex. Nevertheless, BMTI did not perform pharmacokinetics studies to measure the amount and duration of exposure to rhPDGF, and even went so far as to terminate Charlie Hart, its Chief Science Officer, because he pushed BMTI to conduct the studies.

→ BMTI did not perform adequate safety studies revealing the immunological effects from rhPDGF exposure. While PDGF is present in everyone and necessary for proper functioning and growth, rhPDGF is a foreign protein that prompts the production of anti-rhPDGF antibodies and neutralizing antibodies. This is significant because at some point during the study 13.5% of Augment tested positive for ani-rhPDGF antibodies (dropping to 3.9% at six month post-surgery), while only 3.5 of autograft patients were positive for anti-rhPDGF antibodies at some point during the studies (dropping to 1.4% at six months). In contravention of the recommendations of the FDA's Laboratory of Immunology, BMTI did not follow all patients until they reverted to baseline antibody status.

→ BMTI did not perform adequate reproductive toxicology or teratogenicity studies,

> and knew that it could not even begin the necessary studies for several months. These studies are important to show safety for women in child-bearing years because the anti-rhPDGF antibodies or neutralizing antibodies can cross the placenta and disrupt normal fetus development. Without such data, it is impossible to determine how long a woman should refrain from becoming pregnant after Augment because of the potential danger to the fetus.
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> → Augment's reported safety results were falsely enhanced because BMTI did not document and report *all* adverse events in the clinical study as required by the Code of Federal Regulations, and used a vague definition to record and report adverse events by directing investigators not to record events that were considered to be normal consequence of surgery unless the patient required treatment or experience "clinically significant" abnormal swelling, tender, motion at the fusion site or pain with weight bearing. Further, unsuccessful fusions were reported as treatment failures instead of adverse events. Concerns about the insufficiency of the definition for adverse events was brought to BMTI's attention in August and September 2008 during meetings with the data safety monitoring board.

(Docket Entry No. 27, Amended Complaint ¶¶ 40-45, 60-62, 67-79, 82-85, 88-90).

The FDA expressed concerns about Augment and the clinical study in a series of discussions with the Company at various points in the PMA process, and detailed the concerns in a September 3, 2010 Deficiency Letter to BMTI. Specifically regarding the switch from the ITT population to the mITT population, the FDA wrote:

> You have analyzed your primary endpoint in a modified intent to treat (mITT) population. Your original IDE statistical plan states that the primary analysis will be performed using the ITT dataset. . . . You have not provided an adequate justification for using mITT instead of ITT. Modified intent-to-treat analysis allows a subjective approach in entry criteria, which could be biased. Because patients have already been randomized to receive the device, their exclusion and withdrawal for not receiving treatment according to the protocol jeopardizes the baseline comparability of study groups established by randomization.

(Id. ¶ 55). The FDA also raised concerns about the potential link between rhPDGF and the growth of pre-existing, undetected tumors, but BMTI argued Augment did not pose the same dangers as Regranex because the latter is a topical gel that is applied numerous times to a wound, whereas Augment is administered in a single, lower dose. Additionally, in response to the FDA's concern

about the lack of teratology and reproductive toxicology safety studies, BMRI indicated that it was at least 6 to 9 months away such a study in relation to neutralizing antibodies, and disclosed adverse events in Augment patients to be higher in certain categories.

Concerns were also raised by the FDA in briefing documents published on May 10, 2011, in advance of the public meeting before the panel of experts. In those documents, the FDA stated that it "still has clinical concerns with the safety and overall risk/benefit of [Augment] at this time, primarily due to the unanswered question of safety in regards to the potential for cancer formation versus an unproven benefit in the current standard for care." (Id. ¶ 10). The FDA also repeated its concerns about the switch in the population, stating that the "ITT analysis population as defined in the PMA should be considered the primary analysis" because the mITT did no "preserve the benefits of randominization." (Id. ¶ 57). As for BMTI's efforts to distinguish Augment from Regranex, the FDA observed that "no extrapolation can be made regarding the dose and exposure amounts of the PDGF-BB used in Regranex and associated cancer mortality in its comparison to a lower does in exposure being used in Augment." (Id. ¶ 72). Finally, the FDA indicated that the data showed Augment patients experienced more adverse event than autograft patients in certain categories, including immune system disorders, musculoskeletal/connective tissue disorders, arthralgia, pain in extremities, and nervous system disorders.

On May 12, 2010, a public meeting was held before the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee ("the Expert Panel"). After debate, and after some concerns were expressed by certain members[3] as to the possible risks and benefits, the

[3] One panel member remarked that "the minute you start taking patients out of the ITT groups, then you have the possibility of introducing bias[.]" (Id. ¶ 59). Two others were concerned about the lack of pharmacokinetics studies, with one stating their absence was "curiously lacking. . . [a]nd I can't believe we're at this stage of this meeting and ask this question, and we don't know the basic pharmacokinetics of this

Expert Panel voted 10 to 8 in favor of Augments effectiveness, and 12 to 6 in favor of its safety. The narrow vote on the device's benefits and risks "makes it highly unlikely that the device will receive FDA approval without requiring additional trials, incurring substantial costs and delay before the product could be launched." (Docket No. 27, Amended Complaint ¶ 12) .

C. Company's Representations and Market Reaction

Throughout the class period, BMTI painted a rosy picture of the prospects for Augment's approval by the FDA. Such portrayals were made in quarterly and annual reports, earnings calls, and and press releases that prompted both potential investors and market watchers to react.

For example, in a press release issued on October 13, 2009, BMTI announced "positive top-line results" which indicated that patients treated with Augment experienced a similar fusion rate compared with those receiving autograft and that none of the antibodies was neutralizing. In response, BMTI's stock price rose 20% from a closing price of $12.69 on October 13, 2009, to a closing price of $15.32 on October 14, 2009 (Id. ¶¶101-102).

Similar reports about the comparability of fusion rates for Augment and autograft patients were made in BMTI's third quarter financial results, and in an earnings call that date. During the call, Lynch represented that the "top line data clearly demonstrate that Augment and autograph performed equally." (Id. ¶ 106). Lynch also noted what "appear[ed] to be some confusion following the initial release of data concerning the mITT versus ITT patient groups," but proclaimed "there is clearly regulatory precedence in orthopedic devices specifically, for the use of an mITT analysis" and took the "opportunity to once again reinforce that we met our pre-specified primary endpoint

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protein," and another expressing "surprise" at the lack of data and opining that such studies should be pre-market and not post-market. (Id. ¶ 80). The Chair of the panel observed it "a little self-evident that there needs to be further work" on immunogenicity. (Id. at ¶ 87).

and believe that we have demonstrated a clear picture of non-inferiority." (Id.).

In a February 17, 2010 press release announcing the submission of the third module of the PMA, BMTI reiterated the safety and effectiveness of Augment, with Lynch stating, that the company was "very encouraged by the results seen to date in Augment's clinical development program." (Id. ¶ 107). This was followed on March 11 and 12, 2010 by the quarterly and annual reports for the year ending December 31, 2009, with the data said to be based on the mITT patient population "which is the pre-specified primary study population," and which showed that Augment patients exhibited lower rates of serious adverse events, complication, and infection. (Id. ¶¶ 109 & 111). In an earnings call on March 12, 2010, Lynch again reiterated the safety and effectiveness of Augment as compared to autograft, claiming that "substantial additional support" then existed for the previously reported "topline" results, and that "the overall data package for Augment is very robust and has been substantially strengthened as a result of the consistent findings[.]" (Id. ¶ 112).

The quarterly report issued May 10, 2010, indicated that BMTI had provided the FDA with safety data for at least 85% of the Augment study population and that data "demonstrate[d] no new product related serious adverse events or any other safety concern." (Id. ¶ 166-167). This was followed by financial reports filed on August 5, 2010 which again suggested comparable results as between, Augment and autograph, and an absence of any abnormal reactions, with Lynch stating in a conference call that same day that there were really no safety concerns from the FDA about Augment.

The foregoing are just representative samples of the picture BMTI painted of Augment's prospects for success. However, and as already indicated, the FDA provided BMTI with a Deficiency Letter on September 3, 2010, and briefing documents to the Expert Panel on May 10,

2011, both of which expressed concerns about the effectiveness and safety of Augment. Five days after the deficiency letter, BMTI issued a press release entitled "Biomimetic Therapeutics PMA Remains on Track" that stated, in part:

> . . . During its recent discussion with the Company, the FDA raised no unexpected issues that would impact the timing for an upcoming Orthopedic Advisory Panel Meeting or potential approval of Augment. The Company continues to anticipate that the panel meeting will be held by early 2011. If the panel determines the product to be safe and effective, the Company expects approval of Augment by the FDA in mid-2011.
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> * * *
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> "We are pleased with the outcomes of both the 100 day meeting for Augment and the device designation for Augment Injectable," said Dr. Samuel Lynch, president and CEO of BioMimetic Therapeutics. "We feel even more confident in the PMA we submitted for Augment earlier this year."

(Id. ¶ 127).

The briefing documents provided to the Expert Panel that highlighted the FDA's concerns with BMTI's reliance on mITT, the trial's under-powering, the lack of immunogenicity and reproductive toxicology studies, and the reporting of adverse events prompted a downward spiral in BMTI's stock dropping 35% from a May 9, 2010 closing price of $13.39 to a closing price on May 10, 2010 of $8.66 with heavy trading volume. (Id. ¶ 148). It also led to the expression of concern by market watchers about Augment's prospects for approval.

For example, a pharmaceutical analyst for gekkowire.com questioned BMTI's "ability to run a thorough and complete clinical trial for their Augment," because "the FDA appears to be highly concerned that the trial was not run properly," and because "the company did not seek important input from the FDA when several major changes were made to the trial, a big no no in the eyes of the FDA" (Id. ¶ 147). Canaccord Equity echoed such concerns, stating that the briefing documents

were "surprisingly negative in tone and contain discrepancies from prior comments made by management." (Id. ¶ 44). Canaccord also expressed concern about the switch in the patient population, noting that despite BMTI's suggestions, the agreed upon patient population was the ITT population, not the mITT population.

On May 12, 2011, BMTI announced the 10-8 and 12-6 Expert Panel votes, prompting shares to drop nearly 12% from the closing price of $9.20 on May 12th, to the closing price of $8.105 on May 13th. When the FDA posted a summary of the panel meeting some four days later, BMTI shares dropped another 7.4%. (Id. ¶¶ 13 & 153). Several weeks after the FDA posting, J. P. Morgan assigned only a 10% "best case" scenario that Augment would be approved without more study and a 40% "worst case scenario that Augment would required BMTI to go back and do another clinical trial." (Id. 154).

As of the time of filing of the Amended Complaint, Augment had not received FDA approval. In fact, with the response to the Motion to Dismiss, Plaintiffs have included a press release from BMTI dated January 3, 2012 that indicates the FDA, notwithstanding the Expert Panel's recommendation, found Augment was "not approvable" without additional specified information. (Docket No. 41-16 at 1). The release goes on to indicate that "the Company currently anticipates that by mid-2012 it will submit an amendment to the Augment PMA that will include all of the requested additional information," and, if accepted by the FDA, "product approval could occur within 15-24 months[.]" (Id. at 2).

II. STANDARDS OF REVIEW

In considering a Motion to Dismiss a complaint alleging fraud in violation of federal securities law, three standards of review come into play. Those standards derive from Rules

12(b)(6) and 9(c) of the Federal Rules of Civil Procedure, and from the Private Securities Litigation Reform Act of 1995 ("PSLRA").

First, under Rule 12(b)(6), "all well-pleaded material allegations of the pleadings" are accepted as true, and those allegations must "be sufficient to give notice to the defendant as to what claims are alleged, and . . . plead 'sufficient factual matter' to render the legal claim plausible, i.e., more than merely possible." Fritz v. Charter Township of Comstock, 592 F.3d 718, 722 (6th Cir. 2010) (quoting Ashcroft v. Iqbal, 129 S.Ct., 1937, 1949–50 (2009)). In determining whether a complaint sets forth a plausible claim, a court may consider not only the allegations, but "may also consider other materials that are integral to the complaint, are public records, or are otherwise appropriate for the taking of judicial notice." Ley v. Visteon Corp., 543 F.3d 801, 805 (6th Cir. 2008) (citation omitted).

Second, Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "This rule requires a plaintiff: (1) to specify the allegedly fraudulent statements; (2) to identify the speaker; (3) to plead when and where the statements were made; and (4) to explain what made the statements fraudulent." Republic Bank & Trust Co. v. Bear Stearns, 683 F.3d 239, 247 (6th Cir. 2012). "Although 'conditions of a person's mind may be alleged generally,' Fed. R. Civ. P. 9(b), the plaintiff still must plead facts about the defendant's mental state, which, accepted as true, make the state-of-mind allegation 'plausible on its face.'" Id. (quoting, Iqbal, 129 S.Ct. at 1949). (internal quotation marks omitted).

Third, and "[b]olstering this rule of specificity, the PSLRA imposes further pleading requirements." Indiana State Dist. Council of Laborers v. Omnicare, Inc., 583 F.3d 935, 942–43 (6th

Cir. 2009). The "complaint must 'specify each statement alleged to have been misleading,'" along with "the reason or reasons why the statement is misleading,'" and "must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Id. In short, "[a] valid claim under Section 10(b) of the Act and Rule 10b-5 'must allege, in connection with the purchase or sale of securities, the misstatement or omission of a material fact, made with scienter, upon which the plaintiff justifiably relied and which proximately caused the plaintiff's injury.'" Zaluski v. United American Healthcare Corp., 527 F.3d 564, 571 (6th Cir. 2008) (citation omitted).

III. APPLICATION OF LAW

The Court has set forth the allegations in the Amended Complaint in great detail because of the strictures of the PSLRA. Although "the court's job is not to scrutinize each allegation in isolation," it is required "to assess all the allegations holistically." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). This is particularly so with respect to "examining scienter," where a court "must decide whether all of the facts alleged, *taken collectively*, meet the PSLRA's requirements" that there be a "strong inference" of fraudulent intent, that is, the fraudulent intent is "more than merely plausible or reasonable—it [is as] cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" Ashland, Inc. v. Oppenheimer & Co., Inc., 648 F.3d 461, 469 (6th Cir. 2011) (italics in original) (quoting, Tellabs, 551 U.S. at 314). Having undertaken that review, the Court finds that dismissal is warranted.

A.

Prior to delving into the arguments raised in opposition to the motion to dismiss, a few preliminary observations are in order.

A company is not required to divulge to the public each tidbit of information it possesses "because corporations might otherwise 'face potential second-guessing in a subsequent disclosure suit,' a regime that would threaten to 'deluge investors with marginally useful information, and would damage corporations' legitimate needs to keep some information non-public.'" City of Monroe Employees Ret. Sys. v. Bridgestone Corp., 399 F.3d 651, 669 (6th Cir. 2005) (citations omitted). Thus, "[i]n order to be actionable, a misrepresentation or omission must pertain to material information that the defendant had a duty to disclose," id., and generally this duty does not apply to forecasts, or soft information. Zaluski v. United American Healthcare Corp., 527 F.3d 564, 571 (6th Cir. 2008). Moreover, because "[a] misrepresentation or an omission is material only if there is a substantial likelihood that 'a reasonable investor would have viewed the misrepresentation or omission as having significantly altered the total mix of information made available,'" "obviously unimportant," "vague," or "puffing" statements, expressions of "corporate optimism," and "obvious hyperbole" are not actionable. In re Ford Motor Co. Securities Litigation, 381 F.3d 563, 571 (6th Cir. 2004).

With regard to forward-looking statements or forecasts, "a safe-harbor 'excuses liability for defendants' projections, statements of plans and objectives, and estimates of future economic performance.'" Indiana State Dist. Council, 583 F.3d 943 (citation omitted). "This protection is overcome only 'if the statement was material; if defendants had actual knowledge that it was false or misleading; and if the statement was not identified as forward-looking or lacked meaningful cautionary statements.'" Id. Similarly, the failure to disclose "soft information," that is, information which is not "historical" or "objectively verifiable," but rather information consisting of "predictions and matters of opinion" is "'actionable only if it is virtually as certain as hard facts.'" Zaluski, 527

F.3d at 571 (citation omitted).

In moving to dismiss, Defendants first point to a two-column chart they developed that lists dozens of statements made by BMTI and challenged by Plaintiffs. Defendants then provide reasons why, in their opinion, many of the statement are not actionable because they are either forward-looking (*e.g.*, "we are very encouraged by the results seen to date in Augment's clinical development program and look forward to working with the FDA"), or soft (*e.g.*, "we are very pleased with the consistently positive results").

Simply characterizing a statement as either being forward-looking or soft, however, does not mean that liability cannot attach because "[w]hen a company chooses to speak, it must 'provide complete and non-misleading information.'" Indiana State Dist. Council, 583 F.3d at 941 (citation omitted). Thus, "if a company chooses to disclose information about the future, 'its disclosure must be full and fair, and courts may conclude that the company was obliged to disclose additional material facts to the extent that the volunteered disclosure was misleading.'" Zaluski, 527 F.3d at 572. "[E]ven with 'soft information,' a defendant may choose silence or speech based on the then-known factual basis, but it cannot choose half-truths." In re Ford Motor Co. Securities, 381 F.3d at 569.

Here, the underlying premise of the Amended Complaint is that BMTI voluntarily chose to inform the public about the prospects for Augment's approval, but, in doing so, intentionally omitted or withheld certain material facts and provided misleading information. As such, the Court cannot simply disregard a statement because it is talking about the future or because it is a prediction or matter of opinion, but must consider it in the context in which it was made.

B.

In opposing dismissal, Plaintiffs begin by arguing that "[t]his case involves a serious regulatory "bait-and-switch" because, "[t]hroughout the Class Period, Defendants publicly represented that they were using a primary study population in their clinical trial for Augment that was approved by the FDA, when in fact they had switched the study population which was actually in the protocol for the clinical trials filed with the FDA." (Docket No. 44 at 1). A somewhat detailed look at the record is appropriate in regard to this argument because the premise that BMTI engaged in a "bait-and-switch" is at the heart of the Amended Complaint, and drives many of Plaintiffs' arguments.

Plaintiffs argue that "Defendants repeatedly told investors, in press releases, SEC filings and conference calls, that their 'positive top-line' study results were based on findings from an mITT patient population, which Defendants falsely claimed was the 'pre-specified primary study population' that the FDA had approved[.]" (Docket No. 44 at 1). Such statements were allegedly "false when made" because the "FDA approved only ITT as the primary patient population," and "never approved the use of an mITT population for the primary analysis." (Id.). Thus, "[b]y reporting its clinical trial results based on mITT, not the pre-specified ITT, Defendants had no basis to represent they were using a primary study population that was approved by the FDA." (Id.).

Contrary to Plaintiffs' argument, however, BMTI did, in fact, have a basis to represent that a modified intent-to-treat population was the primary study population approved by the FDA. In response to a request from the FDA to correct deficiencies identified in a conditional approval letter, BMTI provided a supplement to its IDE application on April 6, 2007, that included a new protocol which revised the definition of the study's ITT population. Specifically, the new protocol defined the primary pre-specified study population to be "all randomized subjects who receive study

treatment postrandomization. Patients who are randomized and unable to be treated will be considered as surgical screening failures and will not be included in the Intent-to-Treat (ITT) patient population." (Docket No.41-10 at 6). Thus, while the protocol mislabeled the study population as an ITT group, the substantive definition clearly established a modified ITT population that excluded those unable to be treated.

The distinction between the groups and what BMTI was intending to do was not lost on the FDA. In a letter dated May 18, 2007, which approved the protocol just identified, the FDA instructed BMTI to give "serious consideration" to certain specified items, including the following:

> The Intent-to-Treat population should be defined as all randomized subjects in the treatment groups to which they are assigned, regardless [of] whether they actually received the assigned treatment or not. All subjects should be analyzed as randomized even if no treatment or other treatment was actually received. You may analyze additionally a group of patients excluded from the ITT due to "surgical screening failure" . . . however, this should be considered and referred to as a "modified ITT" population versus the "ITT" population (i.e., "true ITT" population) defined above. You should plan to analyze the true ITT population. You may also analyze a modified ITT (i.e., patients with "surgical screening failures" who are excluded from the ITT) and the per-protocol population.

(Docket No. 41-9 at 2).

BMTI was required to follow the protocol approved by the FDA, and Plaintiffs concede as much in their Amended Complaint:

> In order to obtain [FDA] approval, BMTI had to establish in a Premarket Approval Application ("PMA") that Augment is safe and effective, and show that its benefits outweighed its safety risks. The PMA contained data obtained from clinical studies, which *were required to be conducted according to the official protocol accepted by the FDA. As in all PMAs, the version of the protocol accepted by the FDA was binding on BMTI.*

(Docket No. 27 Amended Complaint ¶ 5) (emphasis added). The fact that the FDA told BMTI to give "serious consideration" to certain matters and said several things that should be done, does not

mean that the approved protocol was somehow rejected. See, Fort Worth Employers' Fund v. Biovail Corp., 615 F. Supp.2d 218, 227-28 (S.D.N.Y. 2009) (it "cannot be overstated" that FDA letter did not require certain data, but instead "expressed a non-binding preference for" such data); Noble Asset Mgmt v. Allos Therapeutics, Inc., 2005 WL 4161977 at *7 (D. Colo. Oct. 20, 2005) (defendant's positive statements about the clinical trial results were not misleading "merely because the defendants did not disclose that the FDA had voiced concerns . . about the subgroup analysis").

Moreover, BMTI did not hide the ITT patient study results, and acknowledged the confusion which had been generated between the classifications of patient populations. This disclosure and acknowledgment began right at the start of the class period.

In an October 13, 2009 press release, BMTI announced "positive top-line results from its North American pivotal (Phase III) randomized controlled trial" which "indicate[d] that, with the use of Augment, patients can expect a comparable treatment outcome while being spared the pain and potential morbidity associated with traditional autograft bone harvesting and transplantation." (Docket No. 41-25 at 7). After setting forth "key clinical" statistical evidence indicating that Augment patients "experienced a similar fusion rate" as those receiving an autograft, the press release stated:

> The data above reflect the results of the 397 patient "modified intent-to-treat" (mITT) study population. Thirty seven (37) patients were excluded from this analysis, 21 of which were randomized but never treated and 16 which had major protocol deviations which were prospectively identified (e.g. midfoot fusions even though these were a specific exclusion criteria). Thus, the mITT population represents over 90% of all randomized patients and over 95% of all treated patients.
>
> On a strict intent-to-treat (ITT) population in which those patients who were randomized but never treated are counted as automatic failures, 24 week fusion rates on CT scans were 57.9% for patients randomized to Augment and 60.4% for patients randomized to autograft (p=0.065; n=434). On a per joint basis the CT fusion rate was 65.2% for Augment compared to 64.6% for autograft (p=0.004; n=631).

> Clinical union rate for the ITT population was 79.6% for the Augment group and 79.2% for the autograft group (p=0.004; n=434). The delayed/nonunion rate on the ITT population was 8.1% in the Augment group and 10.7% for the autograft group (p=0.015; n=434).[4]

(Docket No. 41-25 at 6).

The issue of the mITT versus ITT patient population was also the subject of a lot of discussion at a data results conference call between BMTI executives and financial analysts when the press release was issued on October 13, 2009. In fact, after a few prefatory remarks, including the statement that "the clinical results from our North American pivotal clinical trial evaluating the use of Augment Bone Grate in foot and ankle fusions are very strong," Dr. Lynch stated:

> But, before we go too far into the data, let me briefly review an issue that seems to have created some confusion this afternoon, and that is the difference between the MITT and the ITT study populations and the corresponding analyses.
>
> Our protocol clearly defined that the primary analysis would exclude patients who did not receive any treatment under the study. This is customary, and if you look at the infused spine, SS&E, for example, Medtronic did exactly the same thing. That is, their analysis that led to FDA approval was based only on patients that actually received treatment. We included the ITT analysis in the press release because we do also plan to include these data in our PMA, because it is generally accepted to do so.
>
> However, it is also well accepted that the full ITT population contains patients whose results, if included in the analysis, will prevent evaluating the protocol accurately. Patients found not to meet the eligibility criteria who withdrew from the study before receiving any treatment, or who had large amounts of missing data, for example, are often excluded in an MITT analysis.
>
> As long as exclusions are pre-stated and justified, such a modified analysis should provide a more accurate assessment of the trial results. We are extremely pleased with the outcomes of the study so far. While it is important to acknowledge that much more data is still to come, in our opinion these top line results including both CT analyses and clinical endpoints demonstrate that Augment-treated patients had fusion rates at least comparable to autograft without all the pain and morbidity of having to harvest the autograft.

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[4] A "p value" of greater than 0.05 indicates a lack of statistical significance.

(Docket No. 51-1 at 3). Later in the call, during the question and answer period, Dr. Lynch reiterated BMTI's belief that "the MITT analysis that we presented in the most reflective of a very inclusive dataset," representing "over 95% of the treated patients." (Id. at 8). After some further back and forth, an analyst from Rudman Capital Management asked the following:

> . . . I'm quite confused now between what Sam [Lynch] has said and what Dr. DiGiovanni [BMTI's lead investigator for the clinical trials] has said, in this way – does the FDA consider only your ITT statistics and you hope them to consider your MITT statistics? That's my first question.
>
> And the second question is, could you help me understand if we took out these patients who were not treating or treated, what – from the ITT statistics, what would those statistics have been?

(Id. at 12). Before turning the questions over to Russ Pagano, BMTI's Vice President for Clinical and Regulatory Affairs, Dr. Lynch stated, "I think [the analyst's] first question was, does the FDA generally only consider ITT, and we hope they'll consider the MITT?," to which Mr. Pagano responded:

> So, does FDA look at the ITT? No. FDA really looks at the totality of the dataset, and I think if you do that here, regardless of how you weight anything, you would see a classic – kind of classic pattern of a noninferiority outcome in that you're going to have a number of outcomes. If you're truly noninferior to a product in that just typically you're going to have a couple that probably do not make it statistically and hopefully you'll have the bulk that do. So, I think from a statistical point of view, we kind of hit the classic pattern of what you would expect.
>
> FDA – that said, FDA does look at everything. They also said our protocol calls out for we pre-specified, as we talked about the takeouts, if you will, from the MITT. FDA approved that. However, what they do, just to be totally transparent, they frequently in approval letters will put what they call PMA advisories, where they then make some suggestions of things you should do per your PMA. It's in one of these PMA advisories that they state that they also would like to see a true traditional ITT, which basically includes everybody.
>
> They've also told us if we wanted to, we could do a, per-protocol, another (inaudible) analysis. So, they've actually told us they're going to look at just about as much data as they can possibly do . . .

* * *

> So, from the very approval of our protocol, FDA had acknowledged that we have a 10% that we should expect to have roughly a 10% dropout when we do our analyses. I think that is also very strong in our position on the MITT being the correct analysis, both from a regulatory statistical and clinical point of view. I hope that answered question No. 1.
>
> In terms of, I think your second question was basically if you just take out the -- if you just remove the patients who received no treatment from the ITT, what would we have done? That was similar to the question I was asked earlier, and that's where I said our statisticians have actually strongly urged not to do that, because that was not in our plan, and they felt that they would be, then, just -- we would get accused of fishing around for multiple data points. So, we are trying to do analyses that we have said that we would do, and only those analysis we have said we will do.
>
> If the FDA later asked us for additional analyses, obviously we will do that, but then they don't really become post hoc. If we do anything, FDA would consider it to be post hoc analysis.

(Id. at 13).

Based upon the foregoing, the Court sees no basis for holding BMTI liable for securities fraud as a result of the alleged "bait-and-switch." For there to be liability under the PSLRA, there must be the requisite scienter, with that being "a knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." Ashland, Inc., 648 F.3d at 469. Recklessness is defined as highly unreasonable conduct which is an extreme departure from the standards of ordinary care," PR Diamonds, Inc. v. Chandler, 364 F.3d 671, 681 (6th Cir. 2004), and requires "'a mental state apart from negligence and akin to conscious disregard." Louisiana Sch. Employees' Retirement Sys. v. Ernst & Young, LLP, 622 F.3d 471, 480 (6th Cir. 2010).

The press release and subsequent earning call and data results conference do not suggest a knowing and deliberate intent to deceive or defraud, let alone highly unreasonable conduct on the part of BMTI. After all, the announced "positive top-line results" were based upon a study

population that the FDA had approved; the "near miss" of the strict intent-to-treat (ITT) population was revealed; the confusion about the two study population was openly acknowledged; and BMTI made a pitch for why it believed a mITT population study was more accurate, but acknowledged that the FDA would be looking at everything, including "a true traditional ITT, which basically includes everybody results of the true ITT."

BMTI, perhaps, could have characterized things differently, but what it disclosed was sufficient. Under the PSLRA, the failure to disclose must have been material and "'this depends on the significance the reasonable investor would place on the withheld or misrepresented information.'" Zaluski, 527 F.3d at 571 (citation omitted). "That is, a statement is material where there is a 'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" Id. The "total mix" of information includes information in the public domain and facts known or reasonably available to investors. See, Litwin v. Blackstone Group, L.P., 643 F. 3d 706, 718 (2nd Cir. 2011) (collecting cases).

Here, on the heels of the press release and accompanying data call, Reuters issued a report captioned, "BioMimetic's bone product trial disappoints, shrs [sic] tank," and stated that the "augment bone graft shows lower bone fusion vs. autograft," (Docket No. 51-2 at 1) based upon the strict ITT dataset. Two days later, on October 15, 2009, BIOWORLD Today issued a report headlined "BioMimetic Shares Recover as Investors Digest Phase III Data," that indicated shares of BMTI had "been on a roller coaster ride" since the company released its data from the pivotal clinical trial, and that

> the volatility stemmed from investors trying to figure out whether the trial had met its primary endpoint. An analysis of the intent-to-treat population (ITT) showed

> failure, but an analysis of the modified intent-to-treat (mITT) population showed success, and BioMimetic argued that the latter mattered more than the former.

(Docket No. 51-3 at 1). The article went on to state that, even though the company explained why it thought the mITT data was a more accurate result and there was "regulatory precedent" for the use of such a population, "investors were understandably wary as the FDA tend to frown on subset data." (Id. at 2). Thus, market observers recognized the limited value of the positive report.

Finally on the issue of the alleged "bait-and-switch" (and with equal applicability to the other arguments raised by Plaintiffs), it is imperative to note that BMTI never suggested that the approval of Augment by the FDA was assured. Quite the contrary, BMTI repeatedly and consistently warned that there were no guarantees that Augment would be approved and that there were risks and uncertainties in the prospect.[5] In fact, the October 13, 2009 press release contained the following extended disclosures:

> This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of BioMimetic Therapeutics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. There are many important factors that could cause actual results to differ materially from those indicated in the forward-looking statements. BioMimetic Therapeutics' actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with the marketing of BioMimetic Therapeutics' product and product candidates, unproven preclinical and clinical development activities, regulatory oversight and approval, and other risks detailed in BioMimetic Therapeutics' filings with the Securities and Exchange Commission. Companies in the biotechnology industry have suffered significant

[5] Defendants assert that "during the Class Period alone, the Company warned investors *133 times* that investing in a biotech company like BMTI entailed notable and unique risks, including the specific risk that the FDA may not approve of Augment's clinical trials or ultimately approve Augment for clinical use." (Docket No. 40 at 18, italics in original). While the Court has not undertaken the chore of verifying Defendants' calculations, the Court's extensive review of the filings made by the parties reveals that BMTI repeatedly and consistently warned in its SEC filings, press releases, and earnings calls about the risks inherent in the approval process.

> setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Even if favorable data is generated by clinical trials of medical devices, the FDA may not accept or approve a PMA filed by a biotechnology company for such medical devices. Any failure by BioMimetic Therapeutics to obtain FDA approval of Augment, or any of its other product candidates, in a timely manner, or at all, will severely undermine its business and results of operation.

(Docket No. 41-25 at 8). The conference call discussing the results contained in the press release, itself, began with Kearstin Patterson issuing the following disclaimer:

> Before we begin, I would like to remind you that any statements made during this call can be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of BioMimetic Therapeutics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict.
>
> There are many important factors that could cause actual results to differ materially from those indicated in the forward-looking statements. BioMimetic's actual results and the timing and outcome of those events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with the marketing of BioMimetic's product and product candidates, and approved in preclinical and clinical development activity, regulatory oversight and approval, and other risks detailed in the Company's filing with the Securities and Exchange Commission.

(Docket No. 51-1 at 2).

As already indicated, the safe harbor provision of the PSLRA protects forward-looking statements accompanied by meaningful cautionary language. "[I]f the statement qualifies as 'forward-looking' and is accompanied by sufficient cautionary language, a defendant's statement is protected regardless of the actual state of mind." Miller v. Champion Enter., Inc., 346 F.3d 660, 672 (6th Cir. 2003). This protection seems particularly appropos in the context of FDA approval cases because "[e]veryone know that the process of obtaining the FDA's approval for a new drug is fraught with uncertainty," LaSalle v. Medco Research, Inc., 54 F.3d 443, 446 (7th Cir. 1995), and

it "'will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval.'" Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S., 193, 207 (2005) (citation omitted).

C.

In addition to the alleged "bait-and-switch," Plaintiffs contend that "Defendants concealed numerous other serious deficiencies in their conduct of the clinical trials," including that they "did not conduct PK studies in humans, which were necessary to gauge Augment's risk of promoting cancer growth"; "failed to disclose that they had not conducted necessary immogenicity and toxicology studies"; "withheld information from the FDA concerning adverse events they had found"; and "had significantly under-powered [the] clinical studies." (Docket No. 44 at 17 & 19). These alleged deficiencies, Plaintiffs insist, undermined BMTI's representation to investors that the clinical trials were delivering "positive top-line" results.

Leaving aside that the clinical data under the approved protocol were, in fact, showing positive results, and leaving aside that "positive top-line results" might properly be characterized as a protected statement of opinion, see, Kovtun v. Vivus, Inc., 2012 WL 4477647 (N.D. Cal. Sept. 27, 2012) (statement that trials had shown "'remarkable' safety and efficacy" and that results were "compelling" or "excellent" not actionable), the alleged deficiencies and omission in the clinical trials do not raise a strong inference of fraudulent intent as required by the PSLRA.

Garnering FDA approval for a new product or device is, unquestionably an expensive and time-consuming proposition. While Plaintiffs argue that BMTI was cutting corners by failing to conduct certain tests or studies, BMTI's effort to reduce costs does not suggest fraud. After all, Augment was approved in Canada in November 2009 (just after the start of the class period), based

upon the same clinical data submitted to the FDA, and it was appropriate for BMTI to be optimistic that the same result would obtain in the United States, optimism which undoubtedly grew when Augment received Australian regulatory approval in 2011. In re Genzyme Corp., 2012 WL 1076124 at *12 (D. Mass. March 30, 2012); In re AstraZeneca Sec. Litig., 559 F. Supp.2d 453, 471 (S.D.N.Y. 2008) ("approval of [drug] in Europe "made it not unreasonable for defendants to believe in their product"); Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Enxysive Pharm., Inc., 2007 WL 2720074, at *4 (S.D. Tex. Sept.18, 2007) (drugs approval in Europe, Canada, and Australia lent support to company's belief that FDA approval would occur); DeMarco v. Depotech Corp., 149 F. Supp.2d 1212, 1231 (S.D. Cal. 2001) (optimism concerning regulatory approval of [pharmaceutical product] was vindicated, at least in part, by the Canadian government's approval of" the product).[6]

More tellingly, the FDA's expert panel recommended Augment's approval, a recommendation which gave some credence to BMTI's prior optimism. See, In re Cyberonics Inc. Securities Litigation, 2006 WL 2050696 at *8 (S.D. Tex. July 20, 2006) (misrepresentation based upon "alleged failure to disclose FDA concerns about the safety and effectiveness of the . . . device" was "greatly undermined" by virtue of the panel's vote to recommend approval and later issuance of approvable letter). To be sure, the panel vote was not unanimous, and certain concerns were raised by some members as to the lack of certain studies. However, "[t]hat some members of the panel had concerns about the [device] and actually voted not to recommend approval does not alter the fact that the vote resulted in a favorable decision for Defendants." Id. at *7.

[6] This is not to say that the foreign approval process is in anyway the same as the FDA process. See, In re Canadian Import Antitrust 470 F,3d 785, 790 (8th Cir. 2006) (stating that "[d]rugs that are manufactured and distributed in Canada are not approved" in the same was as American drugs, and noting that Congress's plan was "to create a 'closed system' designed to guarantee safe and effective drugs for consumers in the United States").

The notion that BMTI would recklessly forego necessary tests and studies or hide adverse events makes little sense,[7] even disregarding Defendants' assertion that they poured their own money into the company. Plaintiffs' own allegation is that Augment is BMTI's flagship product and necessary to the companies success, begging the question why it would sabotage all of the company's efforts to that point.

It is of note that the only time BMTI held a public stock offering during the class period was months before it received the September 2010 deficiency letter that Plaintiffs claim revealed the FDA's serious concern about the approval of Augment, meaning that the stock offering could not have served as a motive to hide information which had not as yet been received. That aside, "[i]t is rare that a company conducts a public stock offering for any reason other than to raise money and, therefore, this does not raise an inference of scienter," particularly where, as here, the company "used a large part of the money it acquired from the stock sales to finance the development of [its device], indicating Defendants' belief that [the device's] potential as a successful and lucrative product for the company justified the expenditures." Oppenheim Pramerica Asset Management S.A.R.L. v. Encysive Pharmaceuticals, Inc., 2007 WL 2720074 at *5 (S.D. Tex. 2007).

No doubt, BMTI wanted cash and for that needed investors, but that alone does not show scienter to commit fraud. As one court has explained:

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[7] The record actually lends support to Defendants' claim that the company did not intentionally ignore any requirements to conduct certain tests or studies. For example, it appears that the first time it became apparent that the company might be required to conduct a PK study in humans was at the hearing before the panel of experts because, prior to that time, the FDA had indicated that the Augment trials should continue as designed, a design that did not include a human PK study. Further, while Plaintiffs complain about the company's alleged failure to disclose adverse events, the disclosure were sufficient for panel members to comment that the company "did a reasonably good job of reporting the commonly seen or the most important adverse events," with at least one member commenting that "I think that they didn't hide anything." (Docket No. 41-14 at 270-272).

> If scienter could be pleaded merely by alleging that officers and directors possess motive and opportunity to enhance a company's business prospects, virtually every company in the United States that experiences a downturn in stock prices could be forced to defend securities fraud actions. [A company's] alleged desires to obtain favorable financing and to expand abroad are in themselves ordinary and appropriate corporate objectives. Such routine business objectives, without more, cannot normally be motivations for fraud. To hold otherwise would be to support a finding of fraudulent intent for all companies that plan to lower costs and expand sales.

Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1038 (9th Cir. 2012); see, Applestein v. Medivation, Inc., 861 F. Supp.2d 1030, 1041 (N.D. Cal. 2012) ("courts have found that a generic desire to raise capital is insufficient to demonstrate scienter").

Moreover, there is no allegation that the individual defendants received any financial benefit as a result of BMTI's alleged deception. "Stock sales or purchases timed to maximize returns on nonpublic information weigh in favor of inferring scienter; the lack of similar sales weighs against inferring scienter." Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1253 (11th Cir. 2008). "In this case, the amended complaint says nothing about suspicious stock transactions by any of the individual defendants, an omission that weighs against inferring scienter." Id.[8]; see also, Bridgestone, 399 F.3d at 688 (basis for finding scienter diminished where "the Complaint does not allege insider trading at a suspicious time or in an unusual amount"); Pugh v. Tribune Co., 521 F.3d 686, 695 (7th Cir. 2008) (failure to plead that the defendants sold stock at an inflated price negated an inference of scienter); In re K-tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 894 (8th Cir. 2002) ("evidence that the individual defendants abstained from trading may undercut allegations of

[8] The court in Mizzaro went on to observe that, in light of Tellabs, "suspicious stock sales are not necessary to create a strong inference of scienter," but, "[i]nstead, the presence or absence of such allegations must be assessed in light of all of the allegations found in the complaint." Id.

motive").

D.

As should be abundantly clear by now, the Court has throughly reviewed and given extensive thought to the allegations in the Amended Complaint, and finds it necessary to observe but a couple of more things before closing.

First, Plaintiffs make much of the September 2010 deficiency letter and BMTI's press release that was issued some five days later. Plaintiffs argue:

> . . . The Deficiency Letter alone is evidence that Defendants knew full well of the serious deficiencies that plagued their clinical trials, which were not disclosed to investors. In the Deficiency Letter, the FDA told BMTI that it had caught on to their "bait and switch" of the mITT population for the ITT population, and that there was no "adequate justification for using mITT instead of ITT." Unbelievably, just five days after receiving this letter, Defendants issued a press release claiming that the Augment PMA remained "on track," that the FDA had raised "no unexpected issues," and that the Defendants were even more confident with the PMA than ever.

(Docket No. 44 at 2-3).

The fundamental problem with this argument is that it links the Deficiency Letter with the subsequent press release. However, by it very terms, the press release was speaking about the results of the recently held 100 day meeting with the FDA. The press release began with the following:

> BioMimetic Therapeutics, Inc. (NASDAQ: BMTI) today announced it completed its 100 day Premarket Approval Application (PMA) meeting with the Food and Drug Administration (FDA) regarding the review of Augment™ Bone Graft for the treatment of foot and ankle fusions in the U.S. The FDA generally meets with the PMA sponsor approximately 100 days after the filing of the PMA with the purpose of discussing the status of the application. During its recent discussion with the Company, the FDA raised no unexpected issues that would impact the timing for an upcoming Orthopedic Advisory Panel Meeting or potential approval of Augment.

(Docket No. 41-13 at 6). Plaintiffs do not allege that the 100 day meeting raised unexpected issues,

and the Expert Panel meeting did, in fact, occur.

As for the deficiency letter itself, whether a company has an affirmative duty to disclose the scope and content of a deficiency letter appears to be open to question. Compare In re Boston Scientific Corp. Securities Litigation, 490 F. Supp.2d 142, 168 (D. Mass. 2007) (finding no affirmative duty) with Mississippi Public Employees' Retirement System v. Boston Scientific Corp., 523 F.3d 75, 87 (2nd Cir, 2008) (specifically declining to reach the issue on appeal). What is clear, however, is that a deficiency letter is not a final FDA decision, but a request for more information, and, in fact, "very few" PMA are approved without the issuance of a deficiency letter. See, FDA – Industry MDUFA III Reauthorization Meeting, February 9, 2011, http;www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm245176.htm (last visited Jan. 1, 2013). Also clear is that "[i]t simply cannot be that every critical comment by a regulatory agency . . . has to be seen as material for securities law reporting purposes," because "to think otherwise would be to insist on a flood of data that would overwhelm the market and would ironically be, in the end, actually uninformative." In re Genzyme Corp. 2012 WL 1076124 at *10 (D. Mass. Mar. 30, 2012); see also, Noble Asset Mgmt., 2005 WL 4161977 at *7 (citation omitted) ("'Requiring ongoing disclosure of the FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than reporting the questions'"). Withal, after the company's 100 day meeting with the FDA and it written response addressing the deficiency letter, Augment's results were presented to the Expert Panel, just as the company predicted. The FDA did not issue a non-approval or denial order, confirming BMTI's reasonable basis for optimism.

Second, Plaintiffs rely upon three confidential witnesses to support the allegations of fraud. While "anonymous sources are not altogether irrelevant to the scienter analysis," their statements may be discounted and, in some cases, "steeply discounted." Ley, 543 F.3d at 811.

The confidential witness' assertions in this case are not particularly persuasive on the issue of whether Defendants had a fraudulent intent to deceive. Two of the witnesses – CW-1 and CW-3 – left before the start of the class period, suggesting that they could not have known what was in BMTI's corporate mind at the time it issued the challenged statements. Local 295/Local 851 IBT Emplr. Grp. Pension Trust & Welfare Fund v. Fifth Third Bancorp, 731 F. Supp. 2d 689, 722 (S.D. Ohio 2010) ("First, all of CW–2's information pre-dates the class period and, thus, is irrelevant."). The third confidential witness – CW-2 – appears to have been a lower level employee identified as a "document specialist" and then an "associate in the quality assurance department," yet, perhaps remarkably, states "that the decision whether to perform the preclinical or clinical PK studies was so hotly contested that BMTI management fired Hart [the Chief Science Officer] in 2008 because he pushed for the Company to conduct the studies." (Docket No. 27, Amended Complaint ¶¶ 26 & 79).

In any event, the Court has considered all of the statements made by the confidential witnesses and, ignoring those statements which are not particularized or do not show a basis for knowledge, finds that the statements lend support to the notion Dr. Lynch believed Augment would be approved (albeit without additional studies if possible); he was aware of employee's views regarding the Augment study; and there were internal disagreements as to how the clinical trials should be run. But these things do not suggest the failure to disclose material matter or a strong inference of fraudulent intent. Kovtun v. VIVUS, Inc., 2012 WL 4477647 at *18 (N. D. Cal. Sept.

27, 2012) ("Other CWs are alleged to have participated in internal 'debates' about various aspects of the safety of Qnexa or the progress of the clinical trials, but there is nothing ominous or even surprising about employees of a pharmaceutical company that is developing a new drug engaging in discussions about safety issues"); see also, Nathenson v. Zonagen Inc., 267 F.3d 400, 420 (5th Cir. 2001) ("where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols").

E.

In the last sentence of their response brief, Plaintiffs "request leave to amend the Complaint in the event that the Court finds that if falls short of the applicable pleading standard in any respect." (Docket No. 44 at 35). However, "'a bare request in an opposition to a motion to dismiss – without any indication of the particular grounds on which amendment is sought . . . does not constitute a motion within the contemplation of Rule 15(a).'" Louisiana Sch. Employees' Retirement Sys., 663 F.3d at 486 (citation omitted). In the absence of a motion under Rule 15, the Court in its discretion may deny leave to amend because Defendants are "'entitled to a review of the complaint as filed pursuant to Rule 12(b)(6)'" and Plaintiffs are "'not entitled to an advisory opinion from the Court informing them of the deficiencies of the complaint and then an opportunity to cure those deficiencies.'" Id. (citation omitted). Accordingly, Plaintiffs will not be granted leave to amend.

IV. CONCLUSION

Having considered the matter in accordance with the applicable federal rules and the PSLRA, the Court finds that the allegations in the Amended Complaint do not raise an inference of fraudulent

intent or recklessness that is at least as compelling as the opposing inference one could draw from the facts alleged. As such, Defendants' Motion to Dismiss will be granted, and this case will be dismissed.

An appropriate Order will be entered.

Kevin H. Sharp

KEVIN H. SHARP
UNITED STATES DISTRICT JUDGE